**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**AT CHARLESTON**

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| **IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION** | **Master File No. 2:12-MD-02327**<br>**MDL 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

# MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF DONALD R. OSTERGARD, M.D.

Donald R. Ostergard, M.D. seeks to offer various opinions regarding the ability of Prolene, Gynemesh PS, and Prolift products to cause the injuries alleged by the several plaintiffs in this litigation.[1] But this Court's recent rulings—and Dr. Ostergard's own testimony—show that many of these opinions are inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), including:

- **Opinions regarding toxicity and degradation**. Dr. Ostergard's recent admissions on toxicity and degradation show that his testimony on these topics is inadmissible.
- **Opinion that polypropylene is defective when implanted transvaginally.** Dr. Ostergard readily admitted that he uses polypropylene products in precisely this way as part of his most recent clinical practice—and even trains surgery fellows to do so.
- **Opinions regarding safer alternative designs.** Dr. Ostergard admits these opinions lack factual support.
- **Opinions regarding carcinogenicity of polypropylene.** Dr. Ostergard admits he cannot make a causal connection between polypropylene and cancer.
- **Opinions relating to infection, regulatory matters, and corporate knowledge.** This Court has repeatedly excluded this opinion testimony in other cases.

[1] Dr. Ostergard is designated as a general-causation expert for four cases involving TVT products, *see* Motion to Exclude the General Causation Testimony of Donald R. Ostergard, M.D., Ex. A at 1–2, but he does not offer opinions about these products.

As more fully explained below, Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) ask that these opinions be excluded.

## ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

### I. Dr. Ostergard's Recent Admissions Establish that His Opinions Regarding Degradation and Toxicity Are Unreliable and Irrelevant.[2]

While the Court has denied previous motions to exclude Dr. Ostergard's opinions regarding degradation and toxicity of polypropylene, Ethicon's motion is based on new testimony and different grounds. The *Tyree*, *Hall*, and *Wise* motions challenged Dr. Ostergard's polypropylene opinions as unreliable because "(1) they are not generally accepted in the medical community; (2) Dr. Ostergard has not conducted testing to support these theories; and (3) Dr. Ostergard has based his opinions on selective review of scientific literature." *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 551 (S.D.W. Va. 2014), as amended (Oct. 29, 2014); *Hall v. Boston Sci. Corp.*, No. 2:12-CV-08186, 2015 WL 868907, at *22–23 (S.D.W. Va. Feb. 27, 2015); *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *5–7 (S.D.W. Va. Feb. 7, 2015). This motion, in contrast, is based on Dr. Ostergard's recent deposition testimony, in which he

[2] The Court has considered Dr. Ostergard's qualifications to offer opinions regarding polypropylene on several occasions and repeatedly found him sufficiently qualified to testify on these matters. *See, e.g.*, *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 550 (S.D.W. Va. 2014), as amended (Oct. 29, 2014) (adopting ruling in *Jones v. Bard*, No. 2:11–cv–00114 [Docket 391], at 6 (S.D.W. Va. Jan. 6, 2014); *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *6 (S.D.W. Va. Feb. 7, 2015) (same). Ethicon disagrees that Dr. Ostergard is qualified to opine regarding polypropylene. *See*, *e.g.*, Ex. C, Ostergard 3/9/2016 Dep. Tr. 114:17–19 (admitting he is not a biomaterials expert); *id.* at 116:14–16 (admitting he is not an expert in polymer chemistry). Ethicon does not move on this ground, however, given the Court's previous rulings.

admits that he cannot identify the toxins that polypropylene degradation supposedly generates and cannot tie the purported degradation or toxicity to Plaintiffs' injuries. Dr. Ostergard's admitted inability to identify the chemicals supposedly leached from degraded polypropylene or to link the asserted degradation and toxicity to Plaintiffs' injuries renders this testimony inadmissible under *Daubert*.

### A. The Court Should Exclude Dr. Ostergard's Toxicity-Related Opinions as Unreliable, as It Excluded Dr. Pandit's Similar Opinions in *Huskey*.

Dr. Ostergard's admissions regarding the limits of his knowledge of polypropylene toxicity establish that his opinions are no different from opinions of Dr. Abhay Pandit that the Court excluded in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 711 (S.D.W. Va. 2014). In that case, Dr. Pandit proposed to testify that when polypropylene "degrades in vivo, 'chemicals are produced that leach into the surrounding tissues'" and that "Ethicon failed to perform appropriate tests for 'these chemicals and their effects.'" *Id.* The Court excluded these opinions as unreliable on the grounds that Dr. Pandit "was unable to name which particular chemicals are produced" by the purported degradation. *Id*. (citing Dr. Pandit's testimony in which he asserted that "when oxidation occurs breaking the chemical bonds, that chemicals are produced that leach into the surrounding tissues," but admitted, "I'm not so sure which ones they are.")

The Court should do the same here because Dr. Ostergard proposes to offer similar testimony—that polypropylene "contains about 15 additional compounds which are leached from the [polypropylene] and are toxic to tissue[,] which enhances the inflammatory reaction and the intensity of fibrosis." Ex. B, Rule 26 Report of Donald R. Ostergard, M.D. at 3. Yet Dr. Ostergard admits, as Dr. Pandit did, that he cannot identify any such toxins. When asked if he was "aware of any studies in women that show that any toxins lead to significantly higher complication rates for Prolift or Gynemesh PS," Dr. Ostergard responded, "There are no studies

in relation to polypropylene. We don't even know for sure what the toxins are. They haven't been measured, and we do not know if there is increase in adverse events because of it." Ex. C, Ostergard 3/9/16 Dep. Tr. 202:9–18.

Dr. Ostergard's opinions are no more reliable than Dr. Pandit's opinions that were excluded in *Huskey*. Dr. Ostergard proposes to testify that polypropylene degradation releases toxic chemicals, but readily volunteers that he cannot identify any of those toxins. *Id*. His opinions therefore are not "based upon sufficient facts or data," and are inadmissible under *Daubert*. *See Huskey*, 29 F. Supp. 3d at 701. The Court should exclude Dr. Ostergard's degradation and toxicity opinions as unreliable for the same reasons it excluded Dr. Pandit's similar opinions in *Huskey*.

**B. The Court Should Exclude Dr. Ostergard's Opinions Regarding Degradation and Toxicity As Irrelevant Because He Cannot Link Them to Plaintiffs' Injuries.**

An expert's general causation opinions are only admissible if they are "relevant to the task at hand." *Daubert*, 509 U.S. at 597. To be relevant under Rule 702, there must be a "valid scientific connection" between the proposed testimony and "the pertinent inquiry." *Edwards*, 2014 WL 3361923, at *2 (citing *Daubert*, 509 U.S. at 591–92). To meet this "fit" requirement, a court "must ensure that the proposed expert testimony . . . logically advances a material aspect of the proposing party's case." *Daubert v. Merrell Dow Pharm., Inc*. ("*Daubert II*"), 43 F.3d 1311, 1315 (9th Cir. 1995).

To "logically advance" Plaintiffs' cases, Dr. Ostergard's general-causation opinions must provide support for the proposition that the alleged defects in Ethicon's products are capable of causing Plaintiffs' purported injuries. *Id*. at 1315, 1320-22; *see also Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999). As the Eleventh Circuit noted in *McClain v. Metabolife Int'l, Inc.*, "toxic tort cases usually come in two broad categories:" cases in which the

medical community generally recognizes the toxicity of the exposure at issue and those in which it "does not generally recognize the agent as both toxic and causing the injury plaintiff alleges." 401 F.3d 1233, 1239 (11th Cir. 2005) (citing cigarette smoke causing cancer as an example of the first and defendant's combination of ephedrine and caffeine as an example of the second). In *McClain*, plaintiff's expert proposed to testify that ephedrine could cause heart attacks and strokes based on its classification as a sympathomimetic drug, a class of stimulants. *Id*. Based on this general classification, the expert claimed that ephedrine can constrict blood vessels and stimulate the heart, which may raise blood pressure and cause other negative health effects, which in turn may cause heart attacks and strokes. *Id*. at 1240. The expert's "equivocation about the effects" of the exposure in question exposed the "tenuous basis for his opinions about Metabolife's profound toxicity," rendering his opinions inadmissible. *Id*.; *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013) (excluding plaintiffs' expert's general causation opinion as unreliable *ipse dixit* after concluding on a *McClain* analysis that her opinion that transvaginal mesh procedures cause nerve injury and neuropathic pain was "very much in dispute among the medical community").

Dr. Ostergard's testimony is even more tenuous than the *McClain* expert, as Dr. Ostergard cannot make any link at all between the alleged degradation of polypropylene in Ethicon's products, the toxins this degradation supposedly releases, and Plaintiffs' injuries. He readily admitted that "[a]t this point in time, we cannot specifically relate degradation to complications in patients." Ex. C, Ostergard 3/9/16 Dep. Tr. 102:12–14. Similarly, when asked if the clinical manifestation of the alleged degradation would be variable across patients, Dr. Ostergard responded, "Well, since we don't know what the manifestations are, it's very difficult to answer that question." *Id*. at 144:10–16. Because he cannot connect either the alleged

degradation or the hypothesized toxicity it produces to any of the injuries asserted by Plaintiffs in these cases, Dr. Ostergard's testimony regarding degradation and toxicity is inadmissible and should be excluded. *See, e.g.*, *id*. This includes, but is not limited to, the following proposed testimony:

- "The polypropylene is impure. There is no such thing as pure polypropylene (PP). PP contains about 15 additional compounds which are leached from the PP and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis." Ex. B, Ostergard Report at 3.
- "Prolene mesh was shown to be not inert in 2003 with flaking and fissuring demonstrated by scanning electron microscopy." *Id*.
- "With loss of PP due to degradation, the surface area is greatly increased thus providing . . . more elution of toxic compounds from the PP and also the freed toxic PP itself, all of which increases the inflammatory reaction and intensity of fibrosis." *Id*.
- "Heat begins the process of degradation. Gynemesh mesh is cut by a high heat laser." *Id*.
- "Gynemesh mesh produces a persistent foreign body reaction." *Id*.

## II. Dr. Ostergard's Opinion that Polypropylene Is Defective when Used Transvaginally Is Unreliable as It Is Inconsistent with His Clinical Practice.

Dr. Ostergard proposes to testify that the "placement of Gynemesh in the vagina is dangerous to the patient." Ex. B, Ostergard Report at 4. This opinion is unreliable under *Daubert* as it is inconsistent with Dr. Ostergard's clinical practice—experience that undergirds the Court's repeated rulings that Dr. Ostergard is qualified to testify regarding a broad range of subjects in the pelvic mesh litigation. *See, e.g.*, *Tyree*, 54 F. Supp. 3d at 549–50.

The Court has noted that "an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion." *Sanchez v. Boston Scientific Corp*., No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014) *reconsideration denied*, No. 2:12-CV-05762, 2014 WL 5320559 (S.D.W. Va. Oct. 17, 2014).

The Court cautioned, however, that this concern "does have a role in applying *Daubert*" in that the Court considers "whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Id*. (citing *Hoffman v. Monsanto Co.*, No. 2:05–CV–00418, 2007 WL 2984692, at *3 (S.D.W. Va. Oct. 11, 2007)). The Court concluded that it "will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable," but "will consider the independence of an expert's testimony as evidence that his 'research comports with the dictates of good science.'" *Id*. (citing *Daubert II*, 43 F.3d at 1317).

Here, Dr. Ostergard proposes to testify that placement of Gynemesh in the vagina "violates one of the most basic tenets of surgical teachings in that the placement of a permanent implant into the human through a contaminated surgical field (the vagina can never be sterilized) . . . makes the implantation by this route contraindicated." Ex. B, Ostergard Report at 4. This opinion is not specific to Ethicon products, as the subsequent statement regarding C.R. Bard's Avaulta product makes clear. *See id.* ("With Avaulta 96% of the mesh arms were found to be contaminated with bacteria by culture of specimens removed during the surgical procedure"); *see also id*. at 3 (offering opinions regarding polypropylene generally).[3]

Yet Dr. Ostergard testified that he continued to use polypropylene slings in transvaginal procedures, both in his practice and in training surgical fellows, long after he began offering his

[3] Dr. Ostergard purports to base some of his defect-related opinions on small mesh pore sizes, *see* Ex. C, Ostergard 3/9/16 Dep. Tr. 26:8–27:16, but was not aware of the respective pore sizes of mesh products he used as recently as last year and competing Ethicon products. *See id*. at 35:11–15 ("Q. Are you aware that the pore size of TVT is larger than the pore size of SPARC? A: I don't recall—specifically."); *see also* discussion of Dr. Ostergard's use of the SPARC product *infra*.

opinions in mesh litigation. *See, e.g.*, Pl.'s 4/22/2013 Rule 26 Expert Report of Donald Ostergard, M.D., *In re C.R. Bard, Inc.*, No. 2:11-CV-00114, 2013 WL 6142819, at *1 (S.D.W. Va.) (offering opinion that "[p]olyproylene is impure" and other degradation-related opinions). Dr. Ostergard testified that he used the SPARC polypropylene sling transvaginally in his private practice from approximately 2010. *See* Ex. C, Ostergard 3/9/16 Dep. Tr. 34:19–35:4, 36:10–13, 39:14–21; *see also id*. at 36:1013 (re his use of the SPARC product: Q. "But you still left a polypropylene midurethral sling implanted transvaginally in the patients, true? A. That is true."). He also trained fellows at UCLA Harbor View in approximately 2014 to 2015 to use the Boston Scientific Advantage sling. *See id*. at 10:21–11:4, 38:24–39:13.

His ongoing training of the next generation of surgeons in the use of polypropylene mesh products in transvaginal procedures belies his litigation-driven opinions that its use is dangerous for patients. Dr. Ostergard's opinion offered in this litigation cannot be squared with his actual practice and is therefore unreliable. *See Sanchez*, 2014 WL 4851989, at *4. The Court should exclude it under *Daubert*.

## III. Dr. Ostergard's Opinions Regarding Safer Alternative Designs Are Not Reliable Because They Are Not Supported by Sufficient Facts or Data.

Expert testimony is only admissible under Rule 702 if it is "based upon sufficient facts or data"—i.e., if it "rests on a reliable foundation." *See Huskey*, 29 F. Supp. 3d at 701 (citing Rule 702 and *Daubert*, 509 U.S. at 597). Here, Dr. Ostergard proposes to testify regarding safer alternative designs to Gynemesh PS, specifically discussing in his report other meshes that he asserts have favorable characteristics. Indeed, he claims that meshes that are of lighter weight and are less stiff are favorable to Gynemesh PS. *See* Ex. B, Ostergard Report at 3–4 (discussing Polyform, Popmesh, Pelvitex, and Timesh specifically).

But Dr. Ostergard admitted at his deposition that he does not know if any of those meshes have been studied in patients with prolapse in any randomized clinical trials. *See* Ex. C, Ostergard 3/9/16 Dep. Tr. 118:16–119:19. He is not aware of any studies comparing any of these meshes to Gynemesh PS. *Id*. at 119:9–120:12. In fact, he could not recall any studies of women who had undergone implantation of these meshes for treatment of pelvic organ prolapse. *Id*. at 119:5–8, 120:14–17; *see also id*. at 120:22–121:1 ("Q. And you have seen no demonstrable benefit to those meshes compared to Gynemesh PS in women, true? A. I don't think there are any publications on these other meshes); *id*. at 121:13–17 (admitting he did not "investigate the regulatory status of them for the treatment of pelvic organ prolapse in women in this country"). Consistent with these admissions, Dr. Ostergard testified that he is not opining that these meshes are "suitable alternative meshes to Gynemesh PS." *Id*. at 120:18–21.

Based on these admissions, Dr. Ostergard should be precluded from offering opinions regarding safer alternative designs.

## IV. Dr. Ostergard's Admissions Establish that He Cannot Reliably Opine that Polypropylene Causes Cancer.

The Court previously excluded Dr. Ostergard's carcinogenicity opinions because the particular cases did not involve allegations of cancer; accordingly, "the mention of cancer in the context of th[e] case would, at a minimum, offend Federal Rule of Evidence 702 and confuse the jury on a matter with scant probative value." *Wise*, 2015 WL 521202, at *7; *see also Hall*, 2015 WL 868907, at *23 (same); *Tyree*, 54 F. Supp. 3d at 553 (same, citing *Jones v. Bard, Inc., et al*., No. 2:11–cv–00114 [Docket 391], at 8 n.4 (S.D.W. Va. Jan. 6, 2014)).

Although excluded on relevancy grounds in those cases, these same opinions are inadmissible on the additional grounds that they lack "sufficient underlying facts or data." Rule 702. In deposition, Dr. Ostergard discussed "two neoplasms that have been described with

polypropylene mesh." Ex. C, Ostergard 3/9/16 Dep. Tr. 103:2–4. He testified, however, that "there's no proof it causes cancer. It's just an association at this point." *Id*. at 103:8–10. When asked if he intended to testify at trial that Gynemesh PS causes cancer or sarcoma, Dr. Ostergard responded, "I would never testify that it causes cancer. All I could testify to is it has been found in association with cancer." *Id*. at 104:19–24; *see also id*. at 104:25–105:6 (testifying that he did not think he included any such opinions in his report); *id*. at 199:10–11 ("No causation has been established, only association."). And he admitted on further questioning that an association has actually not been established because "there's only been one case reported." *Id*. at 199:12–20.

This testimony establishes that, in addition to excluding Dr. Ostergard's carcinogenicity opinions in cases where cancer is not at issue, they should be excluded more generally as Dr. Ostergard admits that he could not reliably opine that polypropylene causes cancer.

## V. Dr. Ostergard's Opinions Regarding Infection Should Be Excluded in Cases In Which Infection Is Not Alleged.

The Court has excluded opinions regarding mesh-related infections as irrelevant in cases in which the Plaintiff has not alleged infection. *See In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig*., No. 2:12-CV-4301, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied sub nom. In re Ethicon, Inc*., No. 2:12-CV-4301, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014) (excluding infection-related testimony of Plaintiffs' expert Dr. Klinge in case where Plaintiff did not allege infection). An expert witness is only permitted to testify if his or her "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or *to determine a fact in issue*." *Id*. (citing Rule 702) (emphasis in original).

The 20 cases to which Dr. Ostergard's general causation opinions ostensibly apply are listed at Exhibit A. To the extent that any of these cases do not involve infection, Dr. Ostergard's

infection-related testimony should be excluded in those cases. Those opinions include the following:

- "The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages." Ex. B, Ostergard Report at 2–3.

- "With loss of PP due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence . . . which increases the inflammatory reaction and intensity of fibrosis." *Id*. at 3.

- "Predominate infection/inflammation was noted in 2007 in explanted samples from Dr. Cosson's series of patients." *Id*.

- "The large surface area promotes wicking of fluids and bacteria and is a 'bacterial super highway' which provides a safe haven for bacteria which attached themselves to the mesh during the insertion process." *Id*.

- "The size of the mesh placed equates to a very large surface area with many places for bacteria to hide, protected from host defenses." *Id*. at 4.

## VI. Dr. Ostergard Is Not Qualified to Testify Regarding FDA Regulatory Requirements or Warnings.

The Court has considered Dr. Ostergard's testimony regarding FDA regulatory requirements and warnings in previous pelvic mesh cases and limited it based on his qualifications. *See, e.g.*, *Wise*, 2015 WL 521202, at *5. In *Wise*, the Court noted that it had previously found Dr. Ostergard unqualified to opine on FDA regulations and whether a product label satisfies those regulations. *Id*. On plaintiffs' assurance that Dr. Ostergard would not testify on those subjects, the Court allowed Dr. Ostergard to testify in a more limited way "about the risks he perceives that [Bard's] Avaulta poses to patients" and his opinion that "the Avaulta IFU did not convey these risks." *Id*. The Court, however, excluded opinions that went "a step further than comparing the risks of the product to the content of the label" and stated a legal conclusion. *Id*. at *5 n.4. For instance, the Court held that Dr. Ostergard's opinion "that the purported

omissions in the Avaulta IFU rendered the device not reasonably safe" invaded the province of the jury by stating a legal conclusion and would not be accepted at trial. *Id*.

The Court should reach the same conclusion here and exclude the following proposed testimony to the extent that it is inconsistent with the above rulings:

- Dr. Ostergard's testimony that the Prolift IFU is "defective" because it does not say that the training recommended by Ethicon is "required." Ex. C, Ostergard 3/9/16 Dep. Tr. 147:3–10. Dr. Ostergard testified, "I am not aware of any regulatory standard [requiring that surgeons be trained on use of a device], but it does not mean that Ethicon or any other company can't go beyond and make sure that the physicians that are going to use their devices are adequately trained to put the devices in safely." *Id*. at 147:23–148:2.

- "Animal studies were not done using the currently available PP mesh used in Gynemesh. The original prolene mesh studies were not conducted to the steady state where there is no longer any inflammation." Ex. B, Ostergard Report at 3.

- "Ethicon chose what information MD's needed to know in the Professional Education slides." *Id*. at 21.

- "Ethicon chose what information patients needed to know" (citing Prolift Patient Brochure). *Id*.

- "Ethicon made no changes the Prolift IFU after 2008 FDA Communication." *Id*. at 22.

- Testimony based on Dr. Ostergard's narrative review of corporate documents included in the section titled "Other Issues," to the extent that Dr. Ostergard proposes to testify about the relevance or implications of his review of these documents with respect to FDA regulations and whether Ethicon's product labels satisfy those regulations. *Id*. at 25–28.

## VII. Dr. Ostergard's Opinions on Ethicon's Intentions and Narrative Review of Corporate Documents Are Inadmissible.

The Court has repeatedly held that it will not permit expert testimony on "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics," because these matters "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *In re Ethicon, Inc.*, 2014 WL 186872, at *6, *21; *see also, e.g.*, *Wise*, 2015 WL 521202, at *4; *Huskey*, 29. F. Supp. 3d at 703; *In re C.R. Bard*, 948 F. Supp. 2d at 611,

629. In *Huskey*, the Court also excluded expert opinions that offer "simply a narrative review of corporate documents," holding that such "opinions" are not helpful to the jury. *Huskey*, 29 F. Supp. 3d at 706; *see also Sanchez*, 2014 WL 4851989, at *32 (same); *Edwards*, 2014 WL 3361923, at *10 (same).

Despite these rulings, Dr. Ostergard persists in including in his report page after page of proposed testimony on these topics. Consequently, Ethicon respectfully requests that the Court enter rulings here, consistent with its previous rulings, excluding any opinions of Dr. Ostergard (1) regarding Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics or (2) that are merely a narrative review of Ethicon's documents. This includes, but is not limited to, the following proposed testimony:

- Dr. Ostergard's statement, "It concerns me that Ethicon would deliberately not warn doctors about its knowledge of complications arising from implanting its Prolift, Prolift+M, Prolene, Gynemesh, or Gynemesh PS products. As I doctor, I must make decisions to benefit, and not to harm my patients. I need full and accurate information so that I can make those decisions and so that I can fully discuss benefits and risks with my patients. If I cannot rely on information provided by manufacturers, I cannot obtain full and complete consent from my patients and they could suffer harm as a result." Ex. B, Ostergard Report at 28.

- Dr. Ostergard's testimony that the Prolift IFU is "defective" because it does not say that the training recommended by Ethicon is "required." Ex. C, Ostergard 3/9/16 Dep. Tr. 147:3–10. Dr. Ostergard testified, "I am not aware of any regulatory standard [requiring that surgeons be trained on use of a device], but it does not mean that Ethicon or any other company can't go beyond and make sure that the physicians that are going to use their devices are adequately trained to put the devices in safely." *Id.* 147:23–148:2.

- "As indicated by the publication dates in many of the above items, due diligence would have detected all of these mesh defects and helped to predict the complications now known to occur before the introduction of Gynemesh to the medical marketplace. Such adverse events became apparent after patient experimentation paid for by insurance companies." Ex. B, Ostergard Report at 3.

- All of Dr. Ostergard's statements offering a narrative review of Ethicon's corporate documents. *Id.* at 4–8 (items 9.a to 9.nn), 14–18 (items 10.i. to 10.t.; items 11.a. to 11.y.), 22–28(items 17.a. to 18.tt.).

- All of the statements that purport to opine on Ethicon's state of mind, knowledge, motives, or corporate conduct. *Id*. at 4–8 (items 9.a. to 9.nn.), 18–19 (items 12.a. to 12.o.), 19–21 (items 15.a. to 15.u.), 22–28 (items 17.a. to 18.tt.)

**CONCLUSION**

For these reasons stated above, Ethicon asks this Court to grant its Motion to Exclude the General Causation Testimony of Donald R. Ostergard, M.D.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on April 21, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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